



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA-2016-N-0237]

Medical Devices; General and Plastic Surgery Devices; Classification of the Scalp Cooling System to Reduce the Likelihood of Chemotherapy-Induced Alopecia

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the scalp cooling system to reduce the likelihood of chemotherapy-induced alopecia into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the scalp cooling system to reduce the likelihood of chemotherapy-induced alopecia's classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The classification was applicable on December 8, 2015.

FOR FURTHER INFORMATION CONTACT: Neil Ogden, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. G414, Silver Spring, MD 20993-0002, 301-796-6397.

## SUPPLEMENTARY INFORMATION:

### I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1) of the FD&C Act. Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial

equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of “low-moderate risk” or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device.

On March 6, 2015, Target Health, Inc. (on behalf of Dignitana AB) submitted a request for classification of the DigniCap™ Scalp Cooling System under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request and the medical literature, if applicable, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on December 8, 2015, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding § 878.4360 (21 CFR 878.4360).

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for a scalp cooling system to reduce the likelihood of chemotherapy-induced alopecia will need to comply with the special controls named in this final order.

The device is assigned the generic name scalp cooling system to reduce the likelihood of chemotherapy-induced alopecia, and it is identified as a scalp cooling system to reduce the likelihood of chemotherapy-induced alopecia intended to reduce the frequency and severity of alopecia during chemotherapy in which alopecia-inducing chemotherapeutic agents are used. The device is a prescription device.

FDA has identified the following risks to health associated with this type of device and the measures required to mitigate these risks:

Table 1.--Scalp Cooling System to Reduce the Likelihood of Chemotherapy-Induced Alopecia Risks and Mitigation Measures

Identified Risk	Mitigation Measure
Thermal Tissue Damage	Non-clinical Performance Testing Software Verification, Validation, and Hazard Analysis Labeling
Electromagnetic Interference/Electrical Shock	Electromagnetic Compatibility and Electrical Testing Labeling
Adverse Tissue Reaction	Biocompatibility
Increased Risk of Scalp Metastases	Labeling Patient Labeling
Use Error	Labeling
Scalp Pain, Headache, and Chills	Labeling Patient Labeling

FDA believes that the special controls in § 878.4360(b)(1) through (6), in addition to the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness.

Scalp cooling systems to reduce the likelihood of chemotherapy-induced alopecia are prescription devices restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device; see 21 CFR 801.109 (Prescription devices).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the scalp cooling system to reduce the likelihood of chemotherapy-induced alopecia they intend to market.

## II. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## III. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910-0120,

and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910-0485.

#### IV. Reference

The following reference is on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at <http://www.regulations.gov>.

1. DEN150010: De novo request per 513(f)(2) from Target Health, Inc. (on behalf of Dignitana AB), dated March 6, 2015.

#### List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

#### PART 878--GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for 21 CFR part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Add § 878.4360 to subpart E to read as follows:

§ 878.4360 Scalp cooling system to reduce the likelihood of chemotherapy-induced alopecia.

(a) Identification. A scalp cooling system to reduce the likelihood of chemotherapy-induced alopecia is a prescription device intended to reduce the frequency and severity of alopecia during chemotherapy in which alopecia-inducing chemotherapeutic agents are used.

(b) Classification. Class II (special controls). The special controls for this device are:

(1) Non-clinical performance testing must demonstrate that the device meets all design specifications and performance requirements, and that the device performs as intended under anticipated conditions of use. This information must include testing to demonstrate accuracy of the temperature control mechanism.

(2) Performance testing must demonstrate the electromagnetic compatibility and electrical safety of the device.

(3) Software verification, validation, and hazard analysis must be performed.

(4) The patient contacting components of the device must be demonstrated to be biocompatible. Material names must be provided.

(5) Labeling must include the following:

(i) A statement describing the potential risk of developing scalp metastasis.

(ii) Information on the patient population and chemotherapeutic agents/regimen for which the device has been demonstrated to be effective.

(iii) A summary of the non-clinical and/or clinical testing pertinent to use of the device.

(iv) A summary of the device technical parameters, including temperature cooling range and duration of cooling.

(v) A summary of the device- and procedure-related adverse events pertinent to use of the device.

(vi) Information on how the device operates and the typical course of treatment.

(6) Patient labeling must be provided and must include:

(i) Relevant contraindications, warnings, precautions, and adverse effects/complications.

(ii) Information on how the device operates and the typical course of treatment.

(iii) Information on the patient population for which there is clinical evidence of effectiveness.

(iv) The potential risks and benefits associated with use of the device.

(v) Postoperative care instructions.

(vi) A statement describing the potential risk of developing scalp metastasis.

Dated: February 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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